



STATE OF WASHINGTON  
DEPARTMENT OF HEALTH

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October 20, 2005

Petitioners for Pilot Project  
c/o Kathleen Benedict, PLLC  
1235 Fourth Avenue East, Suite 200  
Olympia, Washington 98506

Dear Petitioners and Ms. Benedict:

I am writing this letter to reply to your petition for pilot project rule making filed under the provisions of RCW 34.05.330 and WAC 82-05. The Department of Health denies your petition for several reasons.

Your petition asks the Department of Health (DOH) to change its Certificate of Need (CON) rules through pilot rulemaking to permit Washington hospitals to participate in the *Atlantic C-PORT Trial's* study on elective angioplasty. The study's purpose is to produce scientific data to help determine if it would be safe to perform elective angioplasty at facilities without heart surgery on site.

The role of CON is to use all available data to make reasoned decisions regarding need for additions to the health care system. It is not the role of CON to identify what research is needed, to pass on the validity of proposed new science, to advocate for it, or to fund it. Implementing rules intended for the sole purpose of permitting participation in a research project is outside the scope and responsibility of CON. That would require a system of controls and oversight that is not envisioned in the enabling statutes of CON.

Furthermore, Certificate of Need was created to protect and improve the quality of health care; assure the stability of the health care system; and assure that development of planned services is in response to need. Where there is a need, quality of care is improved by meeting the need, and adequate and appropriately located services promote stability of the system. The petition does not identify a mechanism to assess need for percutaneous coronary intervention. It is not appropriate for CON to permit services to be provided without proven need.

If an appropriate need assessment methodology, such as the recently withdrawn proposed rules on cardiac care, were developed, existing resources of DOH would need to be available to support it. The Department does not have the resources to support this study in the time frame necessary to permit petitioners to participate. To attempt it would negatively affect the CON program in all other functional areas.



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Finally, the pilot rule process is not appropriate for this undertaking. Pilot rules are intended to test "the feasibility of complying with or administering draft new rules... through the use of volunteer pilot groups." In this case, volunteers for such a pilot will involve other parties involuntarily. Such a pilot rule will clearly have an impact on parties who do not volunteer; in fact on parties that have expressed clear opposition to the pilot project.

For these reasons, I must deny your petition for pilot rule making. If you have any questions, please call Laurie Jenkins at (360) 236-4601.

Sincerely,

A handwritten signature in black ink, appearing to read "MC Selecky", written in a cursive style.

Mary C. Selecky  
Secretary

cc: Christina Hulet, Office of Financial Management  
Laurie Jenkins, Department of Health  
Gary Bennett, Department of Health